UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA

Stephanie O'Connor, Ari Silberman, Amanda Hayes and Emily Thompson, **Plaintiffs,** **Vs.** **LVI Global, LLC, d/b/a Las Vegas Institute, Steve Galella, D.D.S., OrthoMatrix Corp., Inc., also d/b/a Facial Beauty Institute, and John's Dental Laboratory, Inc.** **Defendants.**	**CASE NO:** 2:21-CV-00374

PLAINTIFFS' COMPLAINT

Plaintiffs Stephanie O'Connor, Ari Silberman, Amanda Hayes and Emily Thompson, by and through their undersigned counsel, by way of Complaint against LVI Global, LLC d/b/a Las Vegas Institute ("LVI"), John's Dental Laboratory, Inc. ("John's Dental"), Steve Gallella, D.D.S., and OrthoMatrix Corp, Inc., also d/b/a as Facial Beauty Institute ("FBI"), hereby allege as follows:

PARTIES

1. Plaintiff Stephanie O'Connor is an individual and citizen of Ireland, with an address at Northshore Apartments #1227, 110 San Antonio Street, Austin, Texas 78701. At all times relevant to the case, she was and is an adult. Her claims arise from the laws of Indiana and the laws of Germany.

2. Plaintiff Ari Silberman, is an individual and citizen of California, with an address at 147 Hi Point Street, Los Angeles, CA 90035. At all times relevant to the case, he was and is an adult. His claims arise from the law of Indiana and New York.

3. Plaintiff Amanda Hays is an individual and citizen of Arizona with an address at 2927 North Avenida del Conejo, Tucson, Arizona 85749. At all times relevant to the case, she was and is an adult. Her claims arise from the laws of Indiana and Colorado.

4. Plaintiff Emily Thompson is an individual and citizen of the United States, residing at Rudolph Berghs Gade, 50 Copenhagen 2100 Denmark. At all times relevant to the case, she was and is an adult, and is not and has never been a citizen of the states of Nevada, Tennessee or Indiana. Her claims arise from the laws of Indiana and Germany.

5. At all times relevant, defendant LVI was a Nevada limited liability company and a citizen of Nevada with a principal place of business located at 1401 Hillshire Dr. in Las Vegas, Nevada 89134.

6. At all times relevant, defendant John's Dental was an Indiana Corporation and citizen of Indiana with a principal place of business at 423 South 13th Street in Terre Haute, Indiana, 47807.

7. At all relevant times, defendant Dr. Steve Galella, D.D.S. ("Dr. Galella) was an individual and a citizen of Tennessee residing at 997 Eastwood Terrace, Collierville, Tennessee 38017.

8. At all relevant times, defendant OrthoMatrix Corp., Inc. ("OrthoMatrix"), d/b/a as Facial Beauty Institute ("FBI") and d/b/a as OrthoLogic, was a foreign corporation organized under the laws of the State of Tennessee, and a citizen of Tennessee, with a principal place of

business at 875 West Poplar Avenue, Suite 16, Collierville, Tennessee 38017. FBI is a wholly owned division and/or tradename of defendant OrthoMatrix.

PERSONAL JURISDICTION

9. This Court's jurisdiction is based upon diversity of citizenship as set forth in 28 U.S.C. Section 1332 in that all of the plaintiffs are citizens of different states than each of the defendants.

10. The amount in controversy is in excess of Seventy-Five Thousand Dollars ($75,000.00) per plaintiff.

11. Pursuant to 28 U.S.C. 1391, venue is properly laid in this district because a substantial part of the transactions and issues giving rise to plaintiffs' claims occurred in this judicial district.

12. This Court has personal jurisdiction over John's Dental because John's Dental is an Indiana Corporation.

13. This Court has personal jurisdiction over the remaining defendants because they regularly conducted business in Indiana with specific connection to the manufacturing, marketing and sale of the device at issue in this complaint and the claims of plaintiffs.

VENUE

14. Venue is proper in this district because a substantial part of the events or omissions giving rise to the claim occurred in Indiana and because John's Dental is an Indiana entity with a principal place of business in Terre Haute, Indiana.

FACTUAL ALLEGATIONS COMMON TO ALL COUNTS

NATURE OF THE ACTION

15. This is an action for money damages for personal injury suffered by the plaintiffs as the result of the installation of a dental appliance which defendants designed, manufactured and marketed despite no scientific or clinical basis to prove it was either safe or effective.

16. The appliance, known as an "Anterior Growth Guidance Appliance" ("AGGA") was manufactured, designed, and marketed as a proven means of correcting dental, facial and airway abnormalities in lieu of complex jaw surgery for adult patients.

17. Defendants promoted AGGA, taught dentists how it allegedly functioned, and prepared AGGA treatment plans for dentists, claiming that AGGA causes three-dimensional changes in the nasomaxillary complex of adults, including growing/advancing/remodeling the maxilla to move forward horizontally over time by as much or more than 10 mm, through a process of mechanical force and new bone deposition resulting from stimulation of a nerve in the palate, and that it was a reasonable alternative to jaw surgery.

18. Plaintiffs allege that these claims, in regard to adults, are false, and are contrary to medical science; that instead AGGA works in adults, *inter alia*, to push the upper teeth out of their housing in the alveolar bone, that it causes no new bone growth or dimensional changes in the nasomaxillary complex of adults (whose nasomaxillary complex, unlike those of children, have topped growing naturally), that it is not a reasonable alternative to jaw surgery for adults, and that it presents a risk of serious and permanent harm for adults.

19. As a result of the fact that, for adults, AGGA as negligently designed and manufactured was not reasonably safe and was unreasonably dangerous, the promotion and teaching of AGGA involving false representations to dentists including plaintiffs' dentists, the creation of a treatment plan utilizing a product that is unreasonably dangerous to adults, the

failure to warn plaintiffs and/or their dentists about the actual risks of AGGA to adults, and the installation of AGGA in plaintiffs have caused plaintiffs to sustain significant and permanent damage to their teeth and face, economic loss, disfigurement, embarrassment, loss of enjoyment of life, and physical and mental pain and suffering.

FACTS ALLEGED

HISTORY OF AGGA

20. At all times relevant to the case, Dr. Galella was a general dentist duly licensed by the State of Tennessee and a diplomate of an organization called the International Board of Orthodontics.

21. Prior to January 2018, Dr. Galella designed the dental appliances called AGGA and the Controlled Arch system of brackets and wires ("CAB").

22. Prior to 2010, Dr. Galella founded FBI, and at all times relevant to the Complaint Dr. Galella and FBI shared office space in Tennessee, along with OrthoMatrix.

23. Prior to 2010, FBI became an unincorporated division and/or trade name of OrthoMatrix.

24. At all times relevant to the Complaint, LVI claimed to be "an international institution dedicated to the progress of the dental profession through the integration of comprehensive diagnosis, contemporary techniques and technology."

25. At all times relevant to the Complaint, LVI further claimed that the "continuing education offered at LVI is designed to improve the lives of patients and enhance professional satisfaction."

26. At all times relevant to the Complaint, Dr. Galella was an officer of, employed by and working in furtherance of the business of, and/or acted as agent of, FBI and, therefore of OrthoMatrix.

27. At all times relevant to the Complaint, LVI, OrthoMatrix, through its division FBI, and Dr. Galella, offered and taught courses to dentists on the use and alleged safety and efficacy of AGGA and CAB.

28. At all times relevant to the Complaint, OrthoMatrix claimed to be, *inter alia*, a research organization conducting research in various fields including biological mechanisms that cause craniofacial growth in adults.

29. At all times relevant to the Complaint, OrthoMatrix, through its unincorporated division or trade name FBI and/or through another unincorporated division or tradename of OrthoMatrix called OrthoLogic, maintained a program that purported to analyze patients' dental/cranio maxillofacial condition using "radiologists" and "experts" to determine whether said patients were appropriate candidates for AGGA/CAB treatment, and prepare AGGA and CAB treatment plans for such patients with comprehensive instructions that were alleged to be specific and customized for each patient ("the program").

30. Prior to 2010 and at all times relevant to the Complaint, Dr. Galella, LVI, and OrthoMatrix made certain representations ("the representations") to dentists throughout the world, including the dentists who treated the plaintiffs, that:

a. AGGA is a device that causes three-dimensional changes in the nasomaxillary complex of adults, including growing/advancing/remodeling the maxilla to move forward horizontally over time by as much or more than 10 mm;

b. AGGA causes these nasomaxillary changes in adults through a process of mechanical force and new bone deposition resulting from stimulation of a nerve in the palate;

c. as the maxilla moves forward, upper teeth move with it, including in adults;

d. by adhering bite plates to the lower molars, the lower jaw moves forward as the upper jaw moves forward, including in adults;

e. the movement of the jaws has the effect of opening the airway, and moving the jaws into a position more natural for the user's face, including in adults ;

f. AGGA is reasonably safe for installation into dental patients' mouths, including in adults;

g. AGGA can be utilized as a substitute for jaw surgery, including in adults.

31. Prior to 2010 and at all times relevant to the Complaint, Dr. Galella, LVI, and OrthoMatrix, made additional representations to dentist throughout the world, including to dentists treating plaintiffs, that, once AGGA causes the desired maxilla and mandible position to be obtained, and AGGA was then removed, CAB could be used to make relatively minor adjustments in order to guide all teeth to their proper positions, as well as to widen the dental arches, including in adults.

32. The representations, made prior to 2010 and at all times relevant to the Complaint by Dr. Galella, LVI, and OrthoMatrix, were made for the purpose of, *inter alia*, causing dentists to promote AGGA and CAB to consumers, including adult consumers in Germany, New York and Colorado.

33. Neither AGGA nor CAB have ever been submitted to the Federal Drug Administration, or any other government agency, for approval, and they have never been approved by any governmental agency for use in the United States.

34. Dr. Galella, LVI, and OrthoMatrix, knew or should have known that, while the representations may have been true in regard to theue of AGGA by children (who are still growing naturally), the representations as to adults were unproven, not supported by medical knowledge or science, and were false and materially misleading, and that:

a. in adults, AGGA is not a device that can cause changes in the nasomaxillary complex of adults;

b. AGGA is not a device that mechanically causes the maxilla of an adult to move forward horizontally over time as much or more than 10 mm;

c. AGGA does not stimulate new bone growth resulting in dimensional changes to the nasomaxillary complex of an adult;

d. AGGA does not move the maxilla in an adult; instead, it pushes certain of the upper teeth forward over time within the alveolar bone which is attached to the maxilla;

e. in adults, as AGGA pushes the upper teeth forward, the teeth are pushed out of their proper position within the alveolar bone, causing the teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth;

f. AGGA does not open an adult user's airway;

g. AGGA is unreasonably dangerous to adult patients in whom it is installed, and is not reasonably safe for use by such patients; and,

h. AGGA is not a substitute for jaw surgery for adults.

35. At all times relevant to the Complaint, John's Dental was in the business of, *inter alia*, manufacturing, selling and putting into the stream of commerce, dental appliances including

but not limited to AGGA and CAB, and was bound to anticipate that their products would be, through dental professionals, presented to the general public for their use, including but not limited to use by consumers within each state of the United States, Canada, Australia, and within the United Kingdom, as well as within Germany and other countries within the European Union.

36. At all times relevant to the Complaint, John's Dental paid a royalty and/or other fee to both OrthoMatrix and to Galella, or an entity controlled by Galella, for every AGGA device manufactured and sold by John's Dental.

PLAINTIFF AMANDA HAYS

37. Prior to January 2019, dentist Dr. Christopher Sprout ("Dr. Sprout") of Golden, Colorado, took a course in the use, safety and efficacy of AGGA through FBI, which course ("FBI course") was taught by defendant Galella, as well as a similar course on the campus of LVI in Las Vegas, Nevada ("the LVI course").

38. On information and belief, Dr. Sprout paid LVI for the LVI course, and the course was approved by LVI and taught by an LVI-approved instructor.

39. On information and belief, Dr. Sprout paid FBI for the FBI course.

40. During the teaching of the LVI course, the agent, servant or employee of LVI who taught it made various representations about the safety and efficacy of AGGA.

41. During the teaching of the FBI course, Galella made various representations about the safety and efficacy of AGGA.

42. Defendant Galella, individually and as an agent, servant or employee of FBI, and the agent, servant or employee of LVI who taught the LVI course, during the teaching of the FBI course and the LVI course respectively, made various representations about the safety and efficacy of AGGA, which representations included those set forth above and which were

unproven, not supported by medical knowledge or science, untested by any clinical trial, unsupported by peer-reviewed literature, and which were false and materially misleading.

43. On information and belief, the FBI course and/or the LVI course largely or completely comprised the extent of Dr. Sprout's training concerning AGGA and CAB.

44. Prior to January 2019, Ms. Hays sought treatment from Dr. Sprout for, inter alia, improved airway, improved sleep, TMJ and cosmetic issues, and Dr. Sprout prescribed treatment with an AGGA device for the purpose of addressing such issues.

45. At no time did FBI or Galella or LVI ever warn Dr. Sprout or Ms. Hays that, in regard to adult users, AGGA was unproven, was not supported by scientific or medical knowledge, was not reasonably safe, was unreasonably dangerous, was not efficacious, and presented a risk of serious and permanent injury to such consumers.

46. Prior to January 2019, Dr. Sprout consulted with OrthoMatrix, through Dr. Galella and others, in regard to whether Ms. Hays was an appropriate candidate for AGGA and CAB, and for the purpose of establishing an AGGA and CAB treatment plan.

47. More specifically, prior to January 2019, on information and belief, Dr. Sprout submitted a questionnaire and dental records concerning Ms. Hays to OrthoMatrix's Total Diagnostics internet portal, and thereafter and as a result, OrthoMatrix, through Dr. Galella and others, produced an AGGA/CAB treatment plan for Ms. Hays ("the Hays treatment plan") and otherwise represented to Dr. Spout and to Ms. Hays that AGGA and CAB were appropriate treatments for Ms. Hays.

48. Prior to January 2019, Dr. Sprout, on information and belief in reliance on advice, instruction and guidance provided by OrthoMatrix and Dr. Galella, submitted information and/or

specifications to John's Dental concerning Ms. Hays and did place an order for an AGGA appliance to be manufactured by John's Dental for the specific use by Ms. Hays.

49. Prior to January 2019, John's Dental did manufacture an AGGA appliance for use by Dr. Sprout for installation in Ms. O'Connor's mouth, did place it in the stream of commerce and did sell that appliance to Dr. Sprout, who was then within Colorado; John's Dental knew at the time it was placed into the stream of commerce that it would be installed in a member of the public, and specifically that Dr. Sprout would install it in Ms. Hays.

50. At the time of sale of the AGGA to Dr. Sprout, John's Dental impliedly warranted and represented that the AGGA was fit, capable and suitable for the ordinary purposes for which it was intended, that it was fit for the specific purpose for which it was sold to Dr. Sprout, that it had no design defects, that it was of merchantable quality, and that it was safe and not unreasonably dangerous.

51. Ms. Hays reasonably relied upon the implied warranties of John's Dental, as well as on its skill and judgment.

52. Prior to the AGGA being placed into the stream of commerce and sold to Dr. Sprout for use on Ms. Hays, Dr. Galella did inspect and examine photographs of that AGGA device and of a mold of Ms. Hays' teeth, and pronounced the AGGA fit to be used.

53. At the time of the sale of the AGGA to Dr. Sprout, the AGGA was inherently defective by virtue of its design, was not fit for its intended purpose nor for the specific purpose for which it was sold for installation in Ms. Hays' mouth; it was not of merchantable quality, was not reasonably safe, was unreasonably dangerous and defective, all at the time it left the possession, custody and control of John's Dental, for reasons that include but are not limited to:

a. AGGA as designed, manufactured and sold was not based on valid scientific principles, and in an adult does not change the nasomaxillary complex in three, or any, dimensions, does not stimulate new bone growth, does not move the maxilla forward horizontally by as much or more than 10 mm, does not open a user's airway, is in no way a substitute for jaw surgery in an adult;

b. AGGA is unreasonably dangerous in that, rather than move the maxilla or make any three-dimensional changes in the adult nasomaxillary complex, it pushes the upper teeth forward and, after moving more than a limited amount, out of their safe position within the alveolar bone, causing the teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth;

c. While AGGA may have additional utility for children, the utility of AGGA in an adult is in its moving teeth a limited amount within the bone (a function that can be performed by other, standard orthodontic appliances), is far outweighed by the risks AGGA creates;

d. John's Dental failed to warn Dr. Sprout or anyone else:

(i) of the limitations of AGGA's utility for adults in that it would move teeth through bone, but could not make three-dimensional changes in the adult nasomaxillary complex including that it cannot move or grow the maxilla, cannot open an adult user's airway, and is in no way a substitute for jaw surgery in an adult;

(ii) that AGGA should not be used for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move the maxilla;

(iii) that using AGGA for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move or grow the maxilla, could result in serious injury including causing teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth;

(iv) that claims made about AGGA making three-dimensional changes in the nasomaxillary complex of adults were contrary to medical science and unproven; and,

(v) if AGGA were used in an adult, the patient should be closely monitored to ensure it was not causing gum recession, root resorption or other injury indicative of excessive movement of teeth through bone.

54. At the time that John's Dental manufactured, placed into the stream of commerce and sold to Dr. Sprout the AGGA appliance for Ms. Hays, that appliance was not reasonably safe for use on adults, was not minimally safe for its expected purpose, and was dangerous to the extent beyond which would be contemplated by the ordinary dentist or consumer who purchases or uses it, with the ordinary knowledge common to such dentists or users.

55. At all times relevant to the Complaint, had Ms. Hays been warned of the defects and deficiencies of AGGA as described above, she would not have embarked on any course of treatment using AGGA.

56. At all times relevant to the Complaint, had Dr. Sprout been warned by any of the defendants of the defects and deficiencies of AGGA as described above then, on information and belief, he would not have embarked on any course of treatment of Ms. Hays using AGGA.

57. At all times relevant to the Complaint, Ms. Hays would not by exercise of ordinary and reasonable care have discovered the defects and deficiencies of AGGA as described above nor perceived its danger.

58. By the November 2019, Ms. Hays became aware that the AGGA device that had been installed in her was causing severe and permanent injury, and she had the device removed.

59. At all times relevant to the Complaint, Dr. Galella and OrthoMatrix, and LVI, engaged in consumer-related conduct that was materially misleading in that: 1) each of them made material misrepresentations to dentists through the course and other courses, and through website marketing to both dentists and consumers, to the effect that AGGA was safe and efficacious for adults and was a reasonable and functionally effective alternative to jaw surgery for adults that would create three-dimensional changes in the adult nasomaxillary complex including movement of the maxilla; 2) such material misrepresentations were made with the knowledge and expectation that those dentists would advertise and otherwise offer AGGA as a safe and efficacious treatment alternative to adult consumers, including but not limited to consumers in Colorado and Arizona including Ms. Hays; and, 3) such material misrepresentations were made with the knowledge and expectation that adult members of the general public would ask dentists for AGGA and/or otherwise accept AGGA as a safe and efficacious treatment alternative to jaw surgery, and were made to consumers, including but not limited to adult consumers in Arizona and Colorado including Ms. Hays.

60. As a result of the installation and use of the AGGA appliances, Ms. Hays has been caused to suffer significant and permanent injury and damage, including but not limited to: gingival recession, root resorption, bone loss, occlusion, pain, economic loss related to the cost of said worthless and harmful AGGA treatment, prolonged suffering from the conditions for

which she originally sought treatment from Dr. Sprout as a result of being induced to avoid seeking proper treatment for it; and other injury and damage.

61. Ms. Hays at all times relevant to the Complaint acted reasonably, and nothing she did or failed to do caused or contributed to cause her injuries.

COUNT I:

Product Liability-Negligence Against Defendant Dr. Galella

62. Plaintiff Amanda Hays reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

63. Defendant Dr. Galella was negligent in that, *inter alia,* he:

a. Negligently designed the AGGA device that was installed in Ms. Hays for use by adults, when he knew or should have known that AGGA devices, when used by adults to dimensionally change the nasomaxillary complex, were unproven, were neither safe nor efficacious, the principles upon which AGGA allegedly functioned were not supported by and were in contravention of medical knowledge and science, it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by Ms. Hays.

b. taught the course to Dr. Sprout, informing him and others that the AGGA device was safe and efficacious for use by adults, when he knew or should have known that the theory behind AGGA regarding its use on adults and its alleged function of making three-dimensional changes in the nasomaxillary complex including forward movement of the maxilla of adults, was contrary to his education and training, and to medical science, and was unproven, that AGGA was neither safe nor efficacious in regard to making three-dimensional changes in the nasomaxillary complex including forward movement of the maxilla of adults, that it had limited utility for adults, that it

was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by Ms. Hays all as aforesaid; and,

c. marketed AGGA to Dr. Sprout, to Ms. Hays and to dentists and consumers throughout the world, as a product that was safe and efficacious for adults when he knew or should have known that claims made about AGGA making three-dimensional changes in the nasomaxillary complex of adults was contrary to Galella's education and training, and to medical science, and was unproven, that AGGA was neither safe nor efficacious in regard to making three-dimensional changes in the adult nasomaxillary complex including forward movement of the maxilla, had limited utility for adults, that it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by plaintiff, all as aforesaid;

d. failed to warn purchasers of AGGA and dentists to whom he taught the course including Dr. Sprout and other similar courses, or anyone else:

(i) of the limitations of AGGA's utility for adults in that it would move teeth through bone, but could not make three-dimensional changes in the adult nasomaxillary complex including that it cannot move or grow the maxilla, cannot open an adult user's airway, and is in no way a substitute for jaw surgery in an adult;

(ii) that AGGA should not be used for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move the maxilla;

(iii) that using AGGA for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to

move or grow the maxilla, could result in serious injury including, *inter alia,* causing teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth;

(iv) that claims made about AGGA making three-dimensional changes in the nasomaxillary complex of adults were contrary to medical science and unproven; and,

(v) if AGGA were used in an adult, the patient should be closely monitored to ensure it was not causing gum recession, root resorption or other injury indicative of excessive movement of teeth through bone.

64. Dr. Galella acted with reckless disregard for the safety of others, including Ms. Hays.

65. As a direct and proximate result of the negligence of Dr. Galella, and his reckless disregard for the safety of others including Ms. Hays, Ms. Hays has been substantially and permanently injured and damaged as outlined above.

WHEREFORE, plaintiff Amanda Hays demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant Dr. Steve Galella, D.D.S., plus interest and costs.

COUNT II:

Negligence Against Defendant LVI

66. Plaintiff Amanda Hays reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

67. Defendant LVI was negligent in that, *inter alia,* it:

a. taught the course to Dr. Sprout, informing him and others that the AGGA device was safe and efficacious for use by adults, when he knew or should have known

that the theory behind AGGA regarding its use on adults and its alleged function of making three-dimensional changes in the nasomaxillary complex including forward movement of the maxilla of adults, was contrary to his education and training, and to medical science, and was unproven, that AGGA was neither safe nor efficacious in regard to making three-dimensional changes in the nasomaxillary complex including forward movement of the maxilla of adults, that it had limited utility for adults, that it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by Ms. Hays all as aforesaid; and,

b. marketed AGGA to Dr. Sprout, to Ms. Hays and to dentists and consumers throughout the world, as a product that was safe and efficacious for adults when it knew or should have known that claims made about AGGA making three-dimensional changes in the nasomaxillary complex of adults was contrary to medical science, and was unproven, that AGGA was neither safe nor efficacious in regard to making three-dimensional changes in the adult nasomaxillary complex including forward movement of the maxilla, had limited utility for adults, that it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by Ms. Hays, all as aforesaid;

c. failed to warn purchasers of AGGA and dentists to whom it taught the course including Dr. Sprout and other similar courses, or anyone else:

(i) of the limitations of AGGA's utility for adults in that it would move teeth through bone, but could not make three-dimensional changes in the adult nasomaxillary complex including that it cannot move or grow the maxilla,

cannot open an adult user's airway, and is in no way a substitute for jaw surgery in an adult;

(ii) that AGGA should not be used for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move the maxilla;

(iii) that using AGGA for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move or grow the maxilla, could result in serious injury including, inter alia, causing teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth;

(iv) that claims made about AGGA making three-dimensional changes in the nasomaxillary complex of adults were contrary to medical science and unproven; and,

(v) if AGGA were used in an adult, the patient should be closely monitored to ensure it was not causing gum recession, root resorption or other injury indicative of excessive movement of teeth through bone.

68. LVI acted with reckless disregard for the safety of others, including Ms. Hays.

69. As a direct and proximate result of the negligence of LVI, and its reckless disregard for the safety of others including Ms. Hays, Ms. Hays has been substantially and permanently injured and damaged as outlined above.

WHEREFORE, plaintiff Amanda Hays demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant LVI, plus interest and costs.

COUNT III:

Negligence Against Defendant OrthoMatrix And Defendant Galella

70. Plaintiff Amanda Hays reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

71. OrthoMatrix was negligent in that, *inter alia,* it, either directly or by or through its division or trade name FBI and/or OrthoLogic, produced the Hays treatment plan for Ms. Hays' dentist for the installation of an AGGA device, when it knew or should have known that the device, for use by adults, was unproven, it was neither safe nor efficacious, the principles upon which it allegedly functioned were not supported by and were in contravention of medical knowledge and science, it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by Ms. Hays.

72. OrthoMatrix acted with reckless disregard for the safety of others, including Ms. Hays.

73. Galella was negligent in that, *inter alia,* he produced the Hays treatment plan for Ms. Hays' dentist for the installation of an AGGA device, when he knew or should have known that the device, for use by adults, was unproven, it was neither safe nor efficacious, the principles upon which it allegedly functioned were not supported by and were in contravention of medical knowledge and science, it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by Ms. Hays.

74. Galella acted with reckless disregard for the safety of others, including Ms. Hays.

75. As a direct and proximate result of the negligence of OrthoMatrix, and Galella and their reckless disregard for the safety of others including Ms. Hays, Ms. Hays has been substantially and permanently injured and damaged as outlined above.

WHEREFORE, plaintiff Amanda Hays demands Judgment in an amount of in excess of One Hundred Thousand Dollars ($100,000.00) against defendant Orthomatrix Corp., Inc. and defendant Galella, plus interest and costs.

COUNT IV:

Product Liability-Breach Of Warranties Against Defendant John's Dental

76. Plaintiff Amanda Hays reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

77. At the time that the AGGA device that was sold to Ms. Hays' dentist last left the possession, custody or control of John's Dental, the device was inherently defective by virtue of its design, were not fit for its intended purpose nor for the specific purpose for which they were sold for installation in Ms. Hays' mouth, were not of merchantable quality, were not reasonably or minimally safe, and were unreasonably dangerous and defective, all at the time each left the possession, custody and control of John's Dental, for reasons that were described above, in regard to its use by adults.

78. The defective nature of the AGGA devices includes their lack of warnings, at the time each last left the possession, custody and control of defendant John's Dental, in in that it failed to warn purchasers of AGGA, or anyone else:

a. of the limitations of AGGA's utility for adults in that it would move teeth through bone, but could not make three-dimensional changes in the adult nasomaxillary complex including that it cannot move or grow the maxilla, cannot open an adult user's airway, and is in no way a substitute for jaw surgery in an adult;

b. that AGGA should not be used for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move or grow the maxilla;

c. that using AGGA for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move or grow the maxilla, could result in serious injury including causing teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth.

d. that claims made about AGGA making three-dimensional changes in the nasomaxillary complex of adults were contrary to medical science and unproven; and,

e. if AGGA were used in an adult, the patient should be closely monitored to ensure it was not causing gum recession, root resorption or other injury indicative of excessive movement of teeth through bone.

79. When used for the purpose for which it was intended, AGGA has limited utility for adults and presents a risk of serious and permanent injury to adults when used as intended by the designer, manufacturer and seller to make dimensional changes in the nasomaxillary complex, all as aforesaid.

80. As a result of the foregoing, John's Dental was in breach of the implied warranties of merchantability and fitness for a particular purpose in regard to the aforesaid AGGA devices sold to Ms. Hays' dentist and installed in Ms. Hays' mouth.

81. Ms. Hays relied on the aforementioned implied warranties in agreeing to the installation of the AGGA devices.

82. As a direct and proximate result of those breaches of implied warranties, separately and together, Ms. Hays has been substantially and permanently injured and damaged as outlined above.

WHEREFORE, plaintiff Amanda Hays demands Judgment in an amount of in excess of One Hundred Thousand Dollars ($100,000.00) against defendant John's Dental Laboratory, Inc., plus interest and costs.

COUNT V:

Product Liability- Negligence Against Defendant John's Dental

83. Plaintiff Amanda Hays reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

84. At the time the AGGA device was sold by to John's Dental to Ms. Hays' dentist, John's Dental knew or should have known that the device, for use in adults, was not reasonably safe, were negligently designed and in a condition not reasonably contemplated by Ms. Hays, the ultimate user, including for the reasons that the function for which it was designed was not possible to achieve and was in contravention of principles of physiology and anatomy, and carried substantial risk of serious injury for adults.

85. At the time the AGGA device was sold by John's Dental to Ms. Hays' dentist, the product posed a substantial likelihood of harm to Ms. Hays or any other user and was unreasonably dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it with the ordinary knowledge common to consumers, including because the product's tendency when used in adults, rather than to move the maxilla, is to push the upper teeth forward and out of their proper position within the alveolar bone, causing the teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth, all as happened to Ms. Hays as a result of the use of the product.

86. No reasonable person who knew the risk of harm of using AGGA at the time of manufacture would conclude that the benefit of the product outweighed the risk to users.

87. The negligent and defective design of the AGGA device installed in Ms. Hays' mouth was the sole and/or substantial cause and/or factor in bringing about her injuries or damages.

WHEREFORE, plaintiff Amanda Hays demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant John's Dental Laboratory, Inc., plus interest and costs.

COUNT VI:

Colorado Consumer Protection Act Against Defendant John's Dental)

88. Plaintiff Amanda Hays reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

89. Colorado Consumer Legal Remedies Act ("CCLRA"), Colorado Civil Code Section 1750 et seq., makes unlawful any deceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in Colorado.

90. John's Dental has engaged in consumer-oriented conduct that is materially misleading, in that it has, in the course of marketing AGGA to consumers (including Colorado consumers) directly, and to dentists (including Colorado dentists) for the purpose of enticing consumers (including Colorado consumers) to use AGGA, represented falsely that, in regard to adults:

a. AGGA is a device that mechanically causes the maxilla to move forward over time;

b. that by touching and thereby stimulating a nerve in the upper palate, AGGA causes new bone to grow at the maxillary tuberosity (the most distal aspect of the upper jaw) and other places, which in turn causes the maxilla to move forward, effectively lengthening the upper jaw;

c. that as the maxilla moves forward, upper teeth move with it;

d. that by adhering bite plates to the lower molars, the lower jaw moves forward as the upper jaw moves forward;

e. that the movement of the jaws has the effect of opening the airway, and moving the jaws into a position more natural for the user's face;

f. is reasonably safe for installation into dental patients' mouths; and,

g. can be utilized as a substitute for jaw surgery.

91. These false representations are material in that they go to the essence of the function of AGGA as claimed by John's Dental, and their falsity means that the product is useless for the claimed function in adults, i.e. to change the nasomaxillary complex in three dimensions, including advancing the maxilla forward.

92. AGGA is unreasonably dangerous as designed and manufactured, and can cause substantial and permanent damage, as set forth above.

93. As a direct and proximate result of the aforementioned material misrepresentations, Ms. Hays allowed AGGA to be installed in her mouth, and as a result suffered serious and permanent injury as described above.

94. This conduct of John's Dental has affected and will continue to affect not just Ms. Hays but also consumers at large within Colorado who seek to reconfigure their jaws for a host of reasons including resolving issues of insufficient airway, severe dental crowding, disfigurement of chin or jawline or other reasons.

95. This conduct of John's Dental has also affected and will continue to affect Colorado dentists who, based on those misrepresentations, will utilize AGGA on Colorado consumers and thereby visit substantial and permanent injury on such consumers who seek to

reconfigure their jaws for a host of reasons including resolving issues of insufficient airway, severe dental crowding, disfigurement of chin or jawline or other reasons.

96. John's Dental, through its material misrepresentations, has violated CCLRA, thereby causing Ms. Hays severe and permanent injury and damage as described above.

WHEREFORE, plaintiff Amanda Hays demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant John's Dental Laboratory, Inc., plus treble damages, attorney's fees interest and costs.

PLAINTIFF STEPHANIE O'CONNOR

97. Prior to December, 2018, dentist Dr. Charles A. Smith ("Dr. Smith") of Heidelberg, Germany, took a course in the use, safety and efficacy of AGGA through FBI, which course ("FBI course") was taught by defendant Galella, as well as a similar course on the campus of LVI in Las Vegas, Nevada ("the LVI course").

98. On information and belief, Dr. Smith paid LVI for the LVI course, and the course was approved by LVI and taught by an LVI-approved instructor.

99. On information and belief, Dr. Smith paid FBI for the FBI course.

100. During the teaching of the LVI course, the agent, servant or employee of LVI who taught it made various representations about the safety and efficacy of AGGA.

101. During the teaching of the FBI course, Galella made various representations about the safety and efficacy of AGGA.

102. Defendant Galella, individually and as an agent, servant or employee of FBI, and the agent, servant or employee of LVI who taught the LVI course, during the teaching of the FBI course and the LVI course respectively, made various representations about the safety and efficacy of AGGA, which representations included those set forth above and which were

unproven, not supported by medical knowledge or science, untested by any clinical trial, unsupported by peer-reviewed literature, and which were false and materially misleading.

103. On information and belief, the FBI course and/or the LVI course largely or completely comprised the extent of Dr. Smith's training concerning AGGA and CAB.

104. Prior to December 2018, Ms. O'Connor sought treatment from Dr. Smith for a condition which, inter alia, was described as grinding of the teeth at night and waking up in pain in the morning, and Dr. Smith prescribed treatment with an AGGA device for the purpose of curing the root cause of the grinding, described by him as a lack of space in her mouth.

105. At no time did FBI or Galella or LVI ever warn Dr. Smith or Ms. O'Connor that, in regard to adult users, AGGA was unproven, was not supported by scientific or medical knowledge, was not reasonably safe, was unreasonably dangerous, was not efficacious, and presented a risk of serious and permanent injury to such consumers.

106. Prior to December 2018, Dr. Smith consulted with OrthoMatrix, through Dr. Galella and others, in regard to whether Ms. O'Connor was an appropriate candidate for AGGA and CAB, and for the purpose of establishing an AGGA and CAB treatment plan.

107. More specifically, prior to December 2018, on information and belief, Dr. Smith submitted a questionnaire and dental records concerning Ms. O'Connor to OrthoMatrix's Total Diagnostics internet portal, and thereafter and as a result, OrthoMatrix, through Dr. Galella and others, produced an AGGA/CAB treatment plan for Ms. O'Connor ("the O'Connor treatment plan") and otherwise represented to Dr. Smith and to Ms. O'Connor that AGGA and CAB were appropriate treatments for Ms. O'Connor.

108. Prior to December 2018, Dr. Smith, on information and belief in reliance on advice, instruction and guidance provided by OrthoMatrix and Dr. Galella, submitted

information and/or specifications to John's Dental concerning Ms. O'Connor and did place an order for an AGGA appliance to be manufactured by John's Dental for the specific use by Ms. O'Connor.

109. Prior to December 2018, John's Dental did manufacture an AGGA appliance for use by Dr. Smith for installation in Ms. O'Connor's mouth, did place it in the stream of commerce and did sell that appliance to Dr. Smith, who was then within Germany; John's Dental knew at the time it was placed into the stream of commerce that it would be installed in a member of the public, and specifically that Dr. Smith would install it in Ms. O'Connor.

110. At the time of sale of the AGGA to Dr. Smith, John's Dental impliedly warranted and represented that the AGGA was fit, capable and suitable for the ordinary purposes for which it was intended, that it was fit for the specific purpose for which it was sold to Dr. Smith, that it had no design defects, that it was of merchantable quality, and that it was safe and not unreasonably dangerous.

111. Ms. O'Connor reasonably relied upon the implied warranties of John's Dental, as well as on its skill and judgment.

112. Prior to the AGGA being placed into the stream of commerce and sold to Dr. Smith for use on Ms. O'Connor, Dr. Galella did inspect and examine photographs of that AGGA device and of a mold of Ms. O'Connor's teeth, and pronounced the AGGA fit to be used.

113. At the time of the sale of the AGGA to Dr. Smith, the AGGA was inherently defective by virtue of its design, was not fit for its intended purpose nor for the specific purpose for which it was sold for installation in Ms. O'Connor's mouth; it was not of merchantable quality, was not reasonably safe, was unreasonably dangerous and defective, all at the time it left

the possession, custody and control of John's Dental, for reasons that include but are not limited to:

a. AGGA as designed, manufactured and sold was not based on valid scientific principles, and in an adult does not change the nasomaxillary complex in three, or any, dimensions, does not stimulate new bone growth, does not move the maxilla forward horizontally by as much or more than 10 mm, does not open a user's airway, is in no way a substitute for jaw surgery in an adult;

b. AGGA is unreasonably dangerous in that, rather than move the maxilla or make any three-dimensional changes in the adult nasomaxillary complex, it pushes the upper teeth forward and, after moving more than a limited amount, out of their safe position within the alveolar bone, causing the teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth;

c. While AGGA may have additional utility for children, the utility of AGGA in an adult is in its moving teeth a limited amount within the bone (a function that can be performed by other, standard orthodontic appliances), is far outweighed by the risks AGGA creates;

d. John's Dental failed to warn Dr. Smith or anyone else:

(i) of the limitations of AGGA's utility for adults in that it would move teeth through bone, but could not make three-dimensional changes in the adult nasomaxillary complex including that it cannot move or grow the maxilla, cannot open an adult user's airway, and is in no way a substitute for jaw surgery in an adult;

(ii) that AGGA should not be used for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move the maxilla;

(iii) that using AGGA for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move or grow the maxilla, could result in serious injury including causing teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth;

(iv) that claims made about AGGA making three-dimensional changes in the nasomaxillary complex of adults were contrary to medical science and unproven; and,

(v) if AGGA were used in an adult, the patient should be closely monitored to ensure it was not causing gum recession, root resorption or other injury indicative of excessive movement of teeth through bone.

114. At the time that John's Dental manufactured, placed into the stream of commerce and sold to Dr. Smith the AGGA appliance for Ms. O'Connor, that appliance was not reasonably safe for use on adults, was not minimally safe for its expected purpose, and was dangerous to the extent beyond which would be contemplated by the ordinary dentist or consumer who purchases or uses it, with the ordinary knowledge common to such dentists or users.

115. At all times relevant to the Complaint, had Ms. O'Connor been warned of the defects and deficiencies of AGGA as described above, she would not have embarked on any course of treatment using AGGA.

116. At all times relevant to the Complaint, had Dr. Smith been warned by any of the defendants of the defects and deficiencies of AGGA as described above then, on information and belief, he would not have embarked on any course of treatment of Ms. O'Connor using AGGA.

117. At all times relevant to the Complaint, Ms. O'Connor would not by exercise of ordinary and reasonable care have discovered the defects and deficiencies of AGGA as described above nor perceived its danger.

118. By the February of 2019, Ms. O'Connor became aware that the AGGA device that had been installed in her was causing severe and permanent injury, and she later had the device removed.

119. At all times relevant to the Complaint, Dr. Galella and OrthoMatrix, and LVI, engaged in consumer-related conduct that was materially misleading in that: 1) each of them made material misrepresentations to dentists through the course and other courses, and through website marketing to both dentists and consumers, to the effect that AGGA was safe and efficacious for adults and was a reasonable and functionally effective alternative to jaw surgery for adults that would create three-dimensional changes in the adult nasomaxillary complex including movement of the maxilla; 2) such material misrepresentations were made with the knowledge and expectation that those dentists would advertise and otherwise offer AGGA as a safe and efficacious treatment alternative to adult consumers, including but not limited to consumers in Germany including Ms. O'Connor; and, 3) such material misrepresentations were made with the knowledge and expectation that adult members of the general public would ask dentists for AGGA and/or otherwise accept AGGA as a safe and efficacious treatment alternative to jaw surgery, and were made to consumers, including but not limited to adult consumers in Germany including Ms. O'Connor.

120. As a result of the installation and use of the AGGA appliances, Ms. O'Connor has been caused to suffer significant and permanent injury and damage, including but not limited to: gingival recession, bone loss, tooth surface damage, occlusion, tooth decay, tooth sensitivity, pain, economic loss related to the cost of said worthless and harmful AGGA treatment, prolonged suffering from the conditions for which she originally sought treatment from Dr. Smith as a result of being induced to avoid seeking proper treatment for it; and other injury and damage.

121. Ms. O'Connor at all times relevant to the Complaint acted reasonably, and nothing she did or failed to do caused or contributed to cause her injuries.

COUNT VII:

Product Liability-Negligence Against Defendant Dr. Galella

122. Plaintiff Stephanie O'Connor reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

123. Defendant Dr. Galella was negligent in that, *inter alia,* he:

a. Negligently designed the AGGA device that was installed in Ms. O'Connor for use by adults, when he knew or should have known that AGGA devices, when used by adults to dimensionally change the nasomaxillary complex, were unproven, were neither safe nor efficacious, the principles upon which AGGA allegedly functioned were not supported by and were in contravention of medical knowledge and science, it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by Ms. O'Connor;

b. taught the course to Dr. Smith, informing him and others that the AGGA device was safe and efficacious for use by adults, when he knew or should have known that the theory behind AGGA regarding its use on adults and its alleged function of

making three-dimensional changes in the nasomaxillary complex including forward movement of the maxilla of adults, was contrary to his education and training, and to medical science, and was unproven, that AGGA was neither safe nor efficacious in regard to making three-dimensional changes in the nasomaxillary complex including forward movement of the maxilla of adults, that it had limited utility for adults, that it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by Ms. O'Connor all as aforesaid; and,

c. marketed AGGA to Dr. Smith, to Ms. O'Connor and to dentists and consumers throughout the world, as a product that was safe and efficacious for adults when he knew or should have known that claims made about AGGA making three-dimensional changes in the nasomaxillary complex of adults was contrary to Galella's education and training, and to medical science, and was unproven, that AGGA was neither safe nor efficacious in regard to making three-dimensional changes in the adult nasomaxillary complex including forward movement of the maxilla, had limited utility for adults, that it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by plaintiff, all as aforesaid;

d. failed to warn purchasers of AGGA and dentists to whom he taught the course including Dr. Smith and other similar courses, or anyone else:

(i) of the limitations of AGGA's utility for adults in that it would move teeth through bone, but could not make three-dimensional changes in the adult nasomaxillary complex including that it cannot move or grow the maxilla, cannot open an adult user's airway, and is in no way a substitute for jaw surgery in an adult;

(ii) that AGGA should not be used for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move the maxilla;

(iii) that using AGGA for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move or grow the maxilla, could result in serious injury including, *inter alia,* causing teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth;

(iv) that claims made about AGGA making three-dimensional changes in the nasomaxillary complex of adults were contrary to medical science and unproven; and,

(v) if AGGA were used in an adult, the patient should be closely monitored to ensure it was not causing gum recession, root resorption or other injury indicative of excessive movement of teeth through bone.

124. Dr. Galella acted with reckless disregard for the safety of others, including Ms. O'Connor.

125. As a direct and proximate result of the negligence of Dr. Galella, and his reckless disregard for the safety of others including Ms. O'Connor, Ms. O'Connor has been substantially and permanently injured and damaged as outlined above.

WHEREFORE, plaintiff Stephanie O'Connor demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant Dr. Steve Galella, D.D.S., plus interest and costs.

COUNT VIII:

Negligence Against Defendant LVI

126. Plaintiff Stephanie O'Connor reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

127. Defendant LVI was negligent in that, *inter alia,* it:

a. taught the course to Dr. Smith, informing him and others that the AGGA device was safe and efficacious for use by adults, when he knew or should have known that the theory behind AGGA regarding its use on adults and its alleged function of making three-dimensional changes in the nasomaxillary complex including forward movement of the maxilla of adults, was contrary to his education and training, and to medical science, and was unproven, that AGGA was neither safe nor efficacious in regard to making three-dimensional changes in the nasomaxillary complex including forward movement of the maxilla of adults, that it had limited utility for adults, that it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by Ms. O'Connor all as aforesaid; and,

b. marketed AGGA to Dr. Smith, to Ms. O'Connor and to dentists and consumers throughout the world, as a product that was safe and efficacious for adults when it knew or should have known that claims made about AGGA making three-dimensional changes in the nasomaxillary complex of adults was contrary to to medical science, and was unproven, that AGGA was neither safe nor efficacious in regard to making three-dimensional changes in the adult nasomaxillary complex including forward movement of the maxilla, had limited utility for adults, that it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by Ms. O'Connor, all as aforesaid;

c. failed to warn purchasers of AGGA and dentists to whom it taught the course including Dr. Smith and other similar courses, or anyone else:

(i) of the limitations of AGGA's utility for adults in that it would move teeth through bone, but could not make three-dimensional changes in the adult nasomaxillary complex including that it cannot move or grow the maxilla, cannot open an adult user's airway, and is in no way a substitute for jaw surgery in an adult;

(ii) that AGGA should not be used for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move the maxilla;

(iii) that using AGGA for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move or grow the maxilla, could result in serious injury including, inter alia, causing teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth;

(iv) that claims made about AGGA making three-dimensional changes in the nasomaxillary complex of adults were contrary to medical science and unproven; and,

(v) if AGGA were used in an adult, the patient should be closely monitored to ensure it was not causing gum recession, root resorption or other injury indicative of excessive movement of teeth through bone.

128. LVI acted with reckless disregard for the safety of others, including Ms. O'Connor.

129. As a direct and proximate result of the negligence of LVI, and its reckless disregard for the safety of others including Ms. O'Connor, Ms. O'Connor has been substantially and permanently injured and damaged as outlined above.

WHEREFORE, plaintiff Stephanie O'Connor demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant LVI, plus interest and costs.

COUNT IX:

Negligence Against Defendant Orthomatrix And Defendant Galella

130. Plaintiff Stephanie O'Connor reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

131. OrthoMatrix was negligent in that, *inter alia,* it, either directly or by or through its division or trade name FBI and/or OrthoLogic, produced the O'Connor treatment plan for Ms. O'Connor's dentist for the installation of an AGGA device, when it knew or should have known that the device, for use by adults, was unproven, it was neither safe nor efficacious, the principles upon which it allegedly functioned were not supported by and were in contravention of medical knowledge and science, it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by Ms. O'Connor.

132. OrthoMatrix acted with reckless disregard for the safety of others, including Ms. O'Connor.

133. Galella was negligent in that, inter alia, he produced the O'Connor treatment plan for Ms. O'Connor's dentist for the installation of an AGGA device, when he knew or should have known that the device, for use by adults, was unproven, it was neither safe nor efficacious, the principles upon which it allegedly functioned were not supported by and were in

contravention of medical knowledge and science, it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by Ms. O'Connor.

134. Galella acted with reckless disregard for the safety of others, including Ms. O'Connor.

135. As a direct and proximate result of the negligence of OrthoMatrix, and Galella and their reckless disregard for the safety of others including Ms. O'Connor, Ms. O'Connor has been substantially and permanently injured and damaged as outlined above.

WHEREFORE, plaintiff Stephanie O'Connor demands Judgment in an amount of in excess of One Hundred Thousand Dollars ($100,000.00) against defendant OrthoMatrix Corp., Inc. and defendant Galella, plus interest and costs.

COUNT X:

Product Liability-Breach Of Warranties Against Defendant John's Dental

136. Plaintiff Stephanie O'Connor reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

137. At the time that the AGGA device that was sold to Ms. O'Connor's dentist last left the possession, custody or control of John's Dental, the device was inherently defective by virtue of its design, were not fit for its intended purpose nor for the specific purpose for which they were sold for installation in Ms. O'Connor's mouth, were not of merchantable quality, were not reasonably or minimally safe, and were unreasonably dangerous and defective, all at the time each left the possession, custody and control of John's Dental, for reasons that were described above, in regard to its use by adults.

138. The defective nature of the AGGA devices includes their lack of warnings, at the time each last left the possession, custody and control of defendant John's Dental, in in that it failed to warn purchasers of AGGA, or anyone else:

a. of the limitations of AGGA's utility for adults in that it would move teeth through bone, but could not make three-dimensional changes in the adult nasomaxillary complex including that it cannot move or grow the maxilla, cannot open an adult user's airway, and is in no way a substitute for jaw surgery in an adult;

b. that AGGA should not be used for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move or grow the maxilla;

c. that using AGGA for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move or grow the maxilla, could result in serious injury including causing teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth.

d. that claims made about AGGA making three-dimensional changes in the nasomaxillary complex of adults were contrary to medical science and unproven; and,

e. if AGGA were used in an adult, the patient should be closely monitored to ensure it was not causing gum recession, root resorption or other injury indicative of excessive movement of teeth through bone.

139. When used for the purpose for which it was intended, AGGA has limited utility for adults and presents a risk of serious and permanent injury to adults when used as intended by the designer, manufacturer and seller to make dimensional changes in the nasomaxillary complex, all as aforesaid.

140. As a result of the foregoing, John's Dental was in breach of the implied warranties of merchantability and fitness for a particular purpose in regard to the aforesaid AGGA devices sold to Ms. O'Connor's dentist and installed in Ms. O'Connor's mouth.

141. Ms. O'Connor relied on the aforementioned implied warranties in agreeing to the installation of the AGGA devices.

142. As a direct and proximate result of those breaches of implied warranties, separately and together, Ms. O'Connor has been substantially and permanently injured and damaged as outlined above.

WHEREFORE, plaintiff Stephanie O'Connor demands Judgment in an amount of in excess of One Hundred Thousand Dollars ($100,000.00) against defendant John's Dental Laboratory, Inc., plus interest and costs.

COUNT XI:

Product Liability- Negligence Against Defendant John's Dental

143. Plaintiff Stephanie O'Connor reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

144. At the time the AGGA device was sold by to John's Dental to Ms. O'Connor's dentist, John's Dental knew or should have known that the device, for use in adults, was not reasonably safe, were negligently designed and in a condition not reasonably contemplated by Ms. O'Connor, the ultimate user, including for the reasons that the function for which it was designed was not possible to achieve and was in contravention of principles of physiology and anatomy, and carried substantial risk of serious injury for adults.

145. At the time the AGGA device was sold by John's Dental to Ms. O'Connor's dentist, the product posed a substantial likelihood of harm to Ms. O'Connor or any other user and was unreasonably dangerous to an extent beyond that which would be contemplated by the

ordinary consumer who purchases it with the ordinary knowledge common to consumers, including because the product's tendency when used in adults, rather than to move the maxilla, is to push the upper teeth forward and out of their proper position within the alveolar bone, causing the teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth, all as happened to Ms. O'Connor as a result of the use of the product.

146. No reasonable person who knew the risk of harm of using AGGA at the time of manufacture would conclude that the benefit of the product outweighed the risk to users.

147. The negligent and defective design of the AGGA device installed in Ms. O'Connor's mouth was the sole and/or substantial cause and/or factor in bringing about her injuries or damages.

WHEREFORE, plaintiff Stephanie O'Connor demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant John's Dental Laboratory, Inc., plus interest and costs.

COUNT XII:

SECTION 823 OF GERMAN CIVIL CODE AND GERMAN PRODUCT LIABILITY ACT (PRODHAFTG)

148. Plaintiff Stephanie O'Connor reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

149. Section 823 of German Civil Code and the German Product Liability Act make unlawful any deceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in Germany.

150. John's Dental has engaged in consumer-oriented conduct that is materially misleading, in that it has, in the course of marketing AGGA to consumers (including German

consumers) directly, and to dentists (including German dentists) for the purpose of enticing consumers (including German consumers) to use AGGA, represented falsely that:

a. AGGA is a device that mechanically causes the maxilla to move forward over time;

b. that by touching and thereby stimulating a nerve in the upper palate, AGGA causes new bone to grow at the maxillary tuberosity (the most distal aspect of the upper jaw) and other places, which in turn causes the maxilla to move forward, effectively lengthening the upper jaw;

c. that as the maxilla moves forward, upper teeth move with it;

d. that by adhering bite plates to the lower molars, the lower jaw moves forward as the upper jaw moves forward;

e. that the movement of the jaws has the effect of opening the airway, and moving the jaws into a position more natural for the user's face;

f. is reasonably safe for installation into dental patients' mouths; and,

g. can be utilized as a substitute for jaw surgery.

151. These false representations are material in that they go to the essence of the function of AGGA as claimed by John's Dental, and their falsity means that the product is useless.

152. AGGA is unreasonably dangerous as designed and manufactured, and can cause substantial and permanent damage, as set forth above.

153. As a direct and proximate result of the aforementioned material misrepresentations, Ms. O'Connor allowed AGGA to be installed in her mouth, and as a result suffered serious and permanent injury as described above.

154. This conduct of John's Dental has affected and will continue to affect not just Ms. O'Connor but also consumers at large within Germany who seek to reconfigure their jaws for a host of reasons including resolving issues of insufficient airway, severe dental crowding, disfigurement of chin or jawline or other reasons.

155. This conduct of John's Dental has also affected and will continue to affect German dentists who, based on those misrepresentations, will utilize AGGA on German consumers and thereby visit substantial and permanent injury on such consumers who seek to reconfigure their jaws for a host of reasons including resolving issues of insufficient airway, severe dental crowding, disfigurement of chin or jawline or other reasons.

156. John's Dental, through its material misrepresentations, has violated SGA and CPA, thereby causing Ms. O'Connor severe and permanent injury and damage as described above.

WHEREFORE, plaintiff Stephanie O'Connor demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant John's Dental Laboratory, Inc., plus treble damages, attorney's fees interest and costs.

PLAINTIFF ARI SILBERMAN

157. Prior to July 2018, dentist Dr. Martha Cortes ("Dr. Cortes") of New York, took a course in the use, safety and efficacy of AGGA through FBI, which course ("FBI course") was taught by defendant Galella, as well as a similar course on the campus of LVI in Las Vegas, Nevada ("the LVI course").

158. On information and belief, Dr. Cortes paid LVI for the LVI course, and the course was approved by LVI and taught by an LVI-approved instructor.

159. On information and belief, Dr. Cortes paid FBI for the FBI course.

160. During the teaching of the LVI course, the agent, servant or employee of LVI who taught it made various representations about the safety and efficacy of AGGA.

161. During the teaching of the FBI course, Galella made various representations about the safety and efficacy of AGGA.

162. Defendant Galella, individually and as an agent, servant or employee of FBI, and the agent, servant or employee of LVI who taught the LVI course, during the teaching of the FBI course and the LVI course respectively, made various representations about the safety and efficacy of AGGA, which representations included those set forth above and which were unproven, not supported by medical knowledge or science, untested by any clinical trial, unsupported by peer-reviewed literature, and which were false and materially misleading.

163. On information and belief, the FBI course and/or the LVI course largely or completely comprised the extent of Dr. Cortes' training concerning AGGA and CAB.

164. Prior to July 2018, Mr. Silberman sought treatment from Dr. Cortes for conditions which were described as an airway abnormality and sleep apnea and was told he needed to have his jaw moved forward, and Dr. Cortes prescribed treatment with an AGGA device for the purpose of alleviating those conditions and moving his jaw forward.

165. At no time did FBI or Galella or LVI ever warn Dr. Cortes or Mr. Silberman that, in regard to adult users, AGGA was unproven, was not supported by scientific or medical knowledge, was not reasonably safe, was unreasonably dangerous, was not efficacious, and presented a risk of serious and permanent injury to such consumers.

166. Prior to July 2018, on information and belief, Dr. Cortes consulted with OrthoMatrix, through Dr. Galella and others, in regard to whether Mr. Silberman was an

appropriate candidate for AGGA and CAB, and for the purpose of establishing an AGGA and CAB treatment plan.

167. More specifically, prior to July 2018, on information and belief, Dr. Cortes submitted a questionnaire and dental records concerning Mr. Silberman to OrthoMatrix's Total Diagnostics internet portal, and thereafter and as a result, OrthoMatrix, through Dr. Galella and others, produced an AGGA/CAB treatment plan for Mr. Silberman ("the Silberman treatment plan") and otherwise represented to Dr. Cortes and to Mr. Silberman that AGGA and CAB were appropriate treatments for Mr. Silberman.

168. Prior to July 2018, Dr. Cortes, on information and belief in reliance on advice, instruction and guidance provided by OrthoMatrix and Dr. Galella, submitted information and/or specifications to John's Dental concerning Mr. Silberman and did place an order for an AGGA appliance to be manufactured by John's Dental for the specific use by Mr. Silberman.

169. Prior to July 2018, John's Dental did manufacture an AGGA appliance for use by Dr. Cortes for installation in Mr. Silberman's mouth, did place it in the stream of commerce and did sell that appliance to Dr. Cortes, who was then within New York State; John's Dental knew at the time it was placed into the stream of commerce that it would be installed in a member of the public, and specifically that Dr. Cortes would install it in Mr. Silberman.

170. At the time of sale of the AGGA to Dr. Cortes, John's Dental impliedly warranted and represented that the AGGA was fit, capable and suitable for the ordinary purposes for which it was intended, that it was fit for the specific purpose for which it was sold to Dr. Cortes, that it had no design defects, that it was of merchantable quality, and that it was safe and not unreasonably dangerous.

171. Mr. Silberman reasonably relied upon the implied warranties of John's Dental, as well as on its skill and judgment.

172. Prior to the AGGA being placed into the stream of commerce and sold to Dr. Cortes for use on Mr. Silberman, Dr. Galella did inspect and examine photographs of that AGGA device and of a mold of Mr. Silberman's teeth, and pronounced the AGGA fit to be used.

173. At the time of the sale of the AGGA to Dr. Cortes, the AGGA was inherently defective by virtue of its design, was not fit for its intended purpose nor for the specific purpose for which it was sold for installation in Mr. Silberman's mouth; it was not of merchantable quality, was not reasonably safe, was unreasonably dangerous and defective, all at the time it left the possession, custody and control of John's Dental, for reasons that include but are not limited to:

a. AGGA as designed, manufactured and sold was not based on valid scientific principles, and in an adult does not change the nasomaxillary complex in three, or any, dimensions, does not stimulate new bone growth, does not move the maxilla forward horizontally by as much or more than 10 mm, does not open a user's airway, is in no way a substitute for jaw surgery in an adult;

b. AGGA is unreasonably dangerous in that, rather than move the maxilla or make any three-dimensional changes in the adult nasomaxillary complex, it pushes the upper teeth forward and, after moving more than a limited amount, out of their safe position within the alveolar bone, causing the teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth;

c. While AGGA may have additional utility for children, the utility of AGGA in an adult is in its moving teeth a limited amount within the bone (a function that

can be performed by other, standard orthodontic appliances), is far outweighed by the risks AGGA creates;

d. John's Dental failed to warn Dr. Cortes or anyone else:

(i) of the limitations of AGGA's utility for adults in that it would move teeth through bone, but could not make three-dimensional changes in the adult nasomaxillary complex including that it cannot move or grow the maxilla, cannot open an adult user's airway, and is in no way a substitute for jaw surgery in an adult;

(ii) that AGGA should not be used for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move the maxilla;

(iii) that using AGGA for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move or grow the maxilla, could result in serious injury including causing teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth;

(iv) that claims made about AGGA making three-dimensional changes in the nasomaxillary complex of adults were contrary to medical science and unproven; and,

(v) if AGGA were used in an adult, the patient should be closely monitored to ensure it was not causing gum recession, root resorption or other injury indicative of excessive movement of teeth through bone.

174. At the time that John's Dental manufactured, placed into the stream of commerce and sold to Dr. Cortes the AGGA appliance for Mr. Silberman, that appliance was not reasonably safe for use on adults, was not minimally safe for its expected purpose, and was dangerous to the extent beyond which would be contemplated by the ordinary dentist or consumer who purchases or uses it, with the ordinary knowledge common to such dentists or users.

175. At all times relevant to the Complaint, had Mr. Silberman been warned of the defects and deficiencies of AGGA as described above, he would not have embarked on any course of treatment using AGGA.

176. At all times relevant to the Complaint, had Dr. Cortes been warned by any of the defendants of the defects and deficiencies of AGGA as described above then, on information and belief, he would not have embarked on any course of treatment of Mr. Silberman using AGGA.

177. At all times relevant to the Complaint, Mr. Silberman would not by exercise of ordinary and reasonable care have discovered the defects and deficiencies of AGGA as described above nor perceived its danger.

178. By March 2019, Mr. Silberman became aware that the AGGA device that had been installed in him was causing severe and permanent injury, and he later had the device removed.

179. At all times relevant to the Complaint, Dr. Galella and OrthoMatrix, and LVI, engaged in consumer-related conduct that was materially misleading in that: 1) each of them made material misrepresentations to dentists through the course and other courses, and through website marketing to both dentists and consumers, to the effect that AGGA was safe and efficacious for adults and was a reasonable and functionally effective alternative to jaw surgery for adults that would create three-dimensional changes in the adult nasomaxillary complex

including movement of the maxilla; 2) such material misrepresentations were made with the knowledge and expectation that those dentists would advertise and otherwise offer AGGA as a safe and efficacious treatment alternative to adult consumers, including but not limited to consumers in New York State including Mr. Silberman; and, 3) such material misrepresentations were made with the knowledge and expectation that adult members of the general public would ask dentists for AGGA and/or otherwise accept AGGA as a safe and efficacious treatment alternative to jaw surgery, and were made to consumers, including but not limited to adult consumers in New York State including Mr. Silberman.

180. As a result of the installation and use of the AGGA appliances, Mr. Silberman has been caused to suffer significant and permanent injury and damage, including but not limited to: root resorption, bone loss, gingival recession, pain, economic loss related to the cost of said worthless and harmful AGGA treatment, prolonged suffering from the conditions for which he originally sought treatment from Dr. Cortes as a result of being induced to avoid seeking proper treatment for it; and other injury and damage.

181. Mr. Silberman at all times relevant to the Complaint acted reasonably, and nothing he did or failed to do caused or contributed to cause his injuries.

COUNT XIII:

Product Liability-Negligence Against Defendant Dr. Galella

182. Plaintiff Ari Silberman reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

183. Defendant Dr. Galella was negligent in that, *inter alia,* he:

a. Negligently designed the AGGA device that was installed in Mr. Silberman for use by adults, when he knew or should have known that AGGA devices, when used by adults to dimensionally change the nasomaxillary complex, were unproven,

were neither safe nor efficacious, the principles upon which AGGA allegedly functioned were not supported by and were in contravention of medical knowledge and science, it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by Mr. Silberman;

b. taught the course to Dr. Cortes, informing her and others that the AGGA device was safe and efficacious for use by adults, when he knew or should have known that the theory behind AGGA regarding its use on adults and its alleged function of making three-dimensional changes in the nasomaxillary complex including forward movement of the maxilla of adults, was contrary to his education and training, and to medical science, and was unproven, that AGGA was neither safe nor efficacious in regard to making three-dimensional changes in the nasomaxillary complex including forward movement of the maxilla of adults, that it had limited utility for adults, that it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by Mr. Silberman all as aforesaid; and,

c. marketed AGGA to Dr. Cortes, to Mr. Silberman and to dentists and consumers throughout the world, as a product that was safe and efficacious for adults when he knew or should have known that claims made about AGGA making three-dimensional changes in the nasomaxillary complex of adults was contrary to Galella's education and training, and to medical science, and was unproven, that AGGA was neither safe nor efficacious in regard to making three-dimensional changes in the adult nasomaxillary complex including forward movement of the maxilla, had limited utility for adults, that it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by plaintiff, all as aforesaid;

d. failed to warn purchasers of AGGA and dentists to whom he taught the course including Dr. Cortes and other similar courses, or anyone else:

(i) of the limitations of AGGA's utility for adults in that it would move teeth through bone, but could not make three-dimensional changes in the adult nasomaxillary complex including that it cannot move or grow the maxilla, cannot open an adult user's airway, and is in no way a substitute for jaw surgery in an adult;

(ii) that AGGA should not be used for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move the maxilla;

(iii) that using AGGA for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move or grow the maxilla, could result in serious injury including, *inter alia,* causing teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth;

(iv) that claims made about AGGA making three-dimensional changes in the nasomaxillary complex of adults were contrary to medical science and unproven; and,

(v) if AGGA were used in an adult, the patient should be closely monitored to ensure it was not causing gum recession, root resorption or other injury indicative of excessive movement of teeth through bone.

184. Dr. Galella acted with reckless disregard for the safety of others, including Mr. Silberman.

185. As a direct and proximate result of the negligence of Dr. Galella, and his reckless disregard for the safety of others including Mr. Silberman, Mr. Silberman has been substantially and permanently injured and damaged as outlined above.

WHEREFORE, plaintiff Ari Silberman demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant Dr. Steve Galella, D.D.S., plus interest and costs.

COUNT XIV:

Negligence Against Defendant LVI

186. Plaintiff Ari Silberman reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

187. Defendant LVI was negligent in that, *inter alia,* it:

a. taught the course to Dr. Cortes, informing her and others that the AGGA device was safe and efficacious for use by adults, when he knew or should have known that the theory behind AGGA regarding its use on adults and its alleged function of making three-dimensional changes in the nasomaxillary complex including forward movement of the maxilla of adults, was contrary to his education and training, and to medical science, and was unproven, that AGGA was neither safe nor efficacious in regard to making three-dimensional changes in the nasomaxillary complex including forward movement of the maxilla of adults, that it had limited utility for adults, that it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by Mr. Silberman all as aforesaid; and,

b. marketed AGGA to Dr. Cortes, to Mr. Silberman and to dentists and consumers throughout the world, as a product that was safe and efficacious for adults when it knew or should have known that claims made about AGGA making three-

dimensional changes in the nasomaxillary complex of adults was contrary toto medical science, and was unproven, that AGGA was neither safe nor efficacious in regard to making three-dimensional changes in the adult nasomaxillary complex including forward movement of the maxilla, had limited utility for adults, that it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by Mr. Silberman, all as aforesaid;

c. failed to warn purchasers of AGGA and dentists to whom it taught the course including Dr. Cortes and other similar courses, or anyone else:

(i) of the limitations of AGGA's utility for adults in that it would move teeth through bone, but could not make three-dimensional changes in the adult nasomaxillary complex including that it cannot move or grow the maxilla, cannot open an adult user's airway, and is in no way a substitute for jaw surgery in an adult;

(ii) that AGGA should not be used for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move the maxilla;

(iii) that using AGGA for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move or grow the maxilla, could result in serious injury including, inter alia, causing teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth;

(iv) that claims made about AGGA making three-dimensional changes in the nasomaxillary complex of adults were contrary to medical science and unproven; and,

(v) if AGGA were used in an adult, the patient should be closely monitored to ensure it was not causing gum recession, root resorption or other injury indicative of excessive movement of teeth through bone.

188. LVI acted with reckless disregard for the safety of others, including Mr. Silberman.

189. As a direct and proximate result of the negligence of LVI, and its reckless disregard for the safety of others including Mr. Silberman, Mr. Silberman has been substantially and permanently injured and damaged as outlined above.

WHEREFORE, plaintiff Ari Silberman demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant LVI, plus interest and costs.

COUNT XV:

Negligence Against Defendant Orthomatrix And Defendant Galella

190. Plaintiff Ari Silberman reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

191. OrthoMatrix was negligent in that, *inter alia,* it, either directly or by or through its division or trade name FBI and/or OrthoLogic, produced the Silberman treatment plan for Mr. Silberman's dentist for the installation of an AGGA device, when it knew or should have known that the device, for use by adults, was unproven, it was neither safe nor efficacious, the principles upon which it allegedly functioned were not supported by and were in contravention of medical knowledge and science, it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by Mr. Silberman.

192. OrthoMatrix acted with reckless disregard for the safety of others, including Mr. Silberman.

193. Galella was negligent in that, *inter alia,* he produced the Silberman treatment plan for Mr. Silberman's dentist for the installation of an AGGA device, when he knew or should have known that the device, for use by adults, was unproven, it was neither safe nor efficacious, the principles upon which it allegedly functioned were not supported by and were in contravention of medical knowledge and science, it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by Mr. Silberman.

194. Galella acted with reckless disregard for the safety of others, including Mr. Silberman.

195. As a direct and proximate result of the negligence of OrthoMatrix, and Galella and their reckless disregard for the safety of others including Mr. Silberman, Mr. Silberman has been substantially and permanently injured and damaged as outlined above.

WHEREFORE, plaintiff Ari Silberman demands Judgment in an amount of in excess of One Hundred Thousand Dollars ($100,000.00) against defendant Orthomatrix Corp., Inc. and defendant Galella, plus interest and costs.

COUNT XVI:

Product Liability-Breach Of Warranties Against Defendant John's Dental

196. Plaintiff Ari Silberman reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

197. At the time that the AGGA device that was sold to Mr. Silberman's dentist last left the possession, custody or control of John's Dental, the device was inherently defective by virtue of its design, were not fit for its intended purpose nor for the specific purpose for which they were sold for installation in Mr. Silberman's mouth, were not of merchantable quality, were

not reasonably or minimally safe, and were unreasonably dangerous and defective, all at the time each left the possession, custody and control of John's Dental, for reasons that were described above, in regard to its use by adults.

198. The defective nature of the AGGA devices includes their lack of warnings, at the time each last left the possession, custody and control of defendant John's Dental, in in that it failed to warn purchasers of AGGA, or anyone else:

a. of the limitations of AGGA's utility for adults in that it would move teeth through bone, but could not make three-dimensional changes in the adult nasomaxillary complex including that it cannot move or grow the maxilla, cannot open an adult user's airway, and is in no way a substitute for jaw surgery in an adult;

b. that AGGA should not be used for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move or grow the maxilla;

c. that using AGGA for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move or grow the maxilla, could result in serious injury including causing teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth.

d. that claims made about AGGA making three-dimensional changes in the nasomaxillary complex of adults were contrary to medical science and unproven; and,

e. if AGGA were used in an adult, the patient should be closely monitored to ensure it was not causing gum recession, root resorption or other injury indicative of excessive movement of teeth through bone.

199. When used for the purpose for which it was intended, AGGA has limited utility for adults and presents a risk of serious and permanent injury to adults when used as intended by the designer, manufacturer and seller to make dimensional changes in the nasomaxillary complex, all as aforesaid.

200. As a result of the foregoing, John's Dental was in breach of the implied warranties of merchantability and fitness for a particular purpose in regard to the aforesaid AGGA devices sold to Mr. Silberman's dentist and installed in Mr. Silberman's mouth.

201. Mr. Silberman relied on the aforementioned implied warranties in agreeing to the installation of the AGGA devices.

202. As a direct and proximate result of those breaches of implied warranties, separately and together, Mr. Silberman has been substantially and permanently injured and damaged as outlined above.

WHEREFORE, plaintiff Ari Silberman demands Judgment in an amount of in excess of One Hundred Thousand Dollars ($100,000.00) against defendant John's Dental Laboratory, Inc., plus interest and costs.

COUNT XVII:

Product Liability- Negligence Against Defendant John's Dental

203. Plaintiff Ari Silberman reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

204. At the time the AGGA device was sold by to John's Dental to Mr. Silberman's dentist, John's Dental knew or should have known that the device, for use in adults, was not reasonably safe, were negligently designed and in a condition not reasonably contemplated by Ms. O'Connor, the ultimate user, including for the reasons that the function for which it was

designed was not possible to achieve and was in contravention of principles of physiology and anatomy, and carried substantial risk of serious injury for adults.

205. At the time the AGGA device was sold by John's Dental to Mr. Silberman's dentist, the product posed a substantial likelihood of harm to Mr. Silberman or any other user and was unreasonably dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it with the ordinary knowledge common to consumers, including because the product's tendency when used in adults, rather than to move the maxilla, is to push the upper teeth forward and out of their proper position within the alveolar bone, causing the teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth, all as happened to Mr. Silberman as a result of the use of the product.

206. No reasonable person who knew the risk of harm of using AGGA at the time of manufacture would conclude that the benefit of the product outweighed the risk to users.

207. The negligent and defective design of the AGGA device installed Mr. Silberman's mouth was the sole and/or substantial cause and/or factor in bringing about his injuries or damages.

WHEREFORE, plaintiff Ari Silberman demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant John's Dental Laboratory, Inc., plus interest and costs.

COUNT XVIII:

GBL §349 Liability Against Defendant Galella)

208. Plaintiff Ari Silberman reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

209. New York General Business Law §349 makes unlawful any deceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in New York State.

210. Defendant Galella has engaged in consumer-oriented conduct that is materially misleading, in that said defendant has, in the course of marketing AGGA to consumers (including New York consumers) directly, and to dentists (including New York dentists) for the purpose of enticing consumers (including New York consumers) to use AGGA, represented falsely that, in regard to adults:

a. AGGA is a device that causes three-dimensional changes in the nasomaxillary complex of adults, including growing/advancing/remodeling the maxilla to move forward horizontally over time by as much or more than 10 mm;

b. AGGA causes these nasomaxillary changes in adults through a process of mechanical force and new bone deposition resulting from stimulation of a nerve in the palate;

c. as the maxilla moves forward, upper teeth move with it, including in adults;

d. by adhering bite plates to the lower molars, the lower jaw moves forward as the upper jaw moves forward, including in adults;

e. the movement of the jaws has the effect of opening the airway, and moving the jaws into a position more natural for the user's face, including in adults ;

f. AGGA is reasonably safe for installation into dental patients' mouths, including in adults;

g. AGGA can be utilized as a substitute for jaw surgery, including in adults.

211. The aforementioned false representations are material in that they go to the essence of the function of AGGA as claimed by defendant Galella, and their falsity means that the product has limited utility in adults, and that the products risks outweigh utility in adults.

212. AGGA is unreasonably dangerous as designed and manufactured, and can cause substantial and permanent damage, as set forth above.

213. As a direct and proximate result of the aforementioned material misrepresentations, Mr. Silberman allowed AGGA to be installed in his mouth, and as a result suffered serious and permanent injury as described above.

214. The aforementioned conduct of defendant Galella has affected and will continue to affect not just Mr. Silberman but also consumers at large within the State of New York who seek to reconfigure their jaws for a host of reasons including resolving issues of insufficient airway, severe dental crowding, disfigurement of chin or jawline or other reasons.

215. The aforementioned conduct of defendant Galella has also affected and will continue to affect New York dentists who, based on those misrepresentations, will utilize AGGA on adult New York consumers and thereby visit substantial and permanent injury on such consumers who seek to reconfigure their jaws for a host of reasons including resolving issues of insufficient airway, severe dental crowding, disfigurement of chin or jawline or other reasons.

216. Defendant Galella, through his aforementioned material misrepresentations, has violated New York General Business Law §349, thereby causing Mr. Silberman severe and permanent injury and damage as described above.

COUNT XIX:

GBL §349 Liability Against Defendant Orthomatrix

217. Plaintiff Ari Silberman reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

218. New York General Business Law §349 makes unlawful any deceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in New York State.

219. Defendant OrthoMatrix has engaged in consumer-oriented conduct that is materially misleading, in that said defendant has, in the course of marketing AGGA to consumers (including New York consumers) directly, and to dentists (including New York dentists) for the purpose of enticing consumers (including New York consumers) to use AGGA, represented falsely that, in regard to adults:

a. AGGA is a device that causes three-dimensional changes in the nasomaxillary complex of adults, including growing/advancing/remodeling the maxilla to move forward horizontally over time by as much or more than 10 mm;

b. AGGA causes these nasomaxillary changes in adults through a process of mechanical force and new bone deposition resulting from stimulation of a nerve in the palate;

c. as the maxilla moves forward, upper teeth move with it, including in adults;

d. by adhering bite plates to the lower molars, the lower jaw moves forward as the upper jaw moves forward, including in adults;

e. the movement of the jaws has the effect of opening the airway, and moving the jaws into a position more natural for the user's face, including in adults ;

f. AGGA is reasonably safe for installation into dental patients' mouths, including in adults;

g. AGGA can be utilized as a substitute for jaw surgery, including in adults.

220. The aforementioned false representations are material in that they go to the essence of the function of AGGA as claimed by defendant OrthoMatrix, and their falsity means that the product has limited utility in adults, and that the products risks outweigh utility in adults.

221. AGGA is unreasonably dangerous as designed and manufactured, and can cause substantial and permanent damage, as set forth above.

222. As a direct and proximate result of the aforementioned material misrepresentations, Mr. Silberman allowed AGGA to be installed in his mouth, and as a result suffered serious and permanent injury as described above.

223. The aforementioned conduct of defendant OrthoMatrix has affected and will continue to affect not just Mr. Silberman but also consumers at large in the State of New York who seek to reconfigure their jaws for a host of reasons including resolving issues of insufficient airway, severe dental crowding, disfigurement of chin or jawline or other reasons.

224. The aforementioned conduct of defendant OrthoMatrix has also affected and will continue to affect New York dentists who, based on those misrepresentations, will utilize AGGA on adult New York consumers and thereby visit substantial and permanent injury on such consumers who seek to reconfigure their jaws for a host of reasons including resolving issues of insufficient airway, severe dental crowding, disfigurement of chin or jawline or other reasons.

225. Defendant OrthoMatrix, through its aforementioned material misrepresentations, has violated New York General Business Law §349, thereby causing Mr. Silberman severe and permanent injury and damage as described above.

PLAINTIFF EMILY THOMPSON

226. Prior to November, 2018, the aforementioned dentist Dr. Charles A. Smith ("Dr. Smith") of Heidelberg, Germany, took a course in the use, safety and efficacy of AGGA through

FBI, which course ("FBI course") was taught by defendant Galella, as well as a similar course on the campus of LVI in Las Vegas, Nevada ("the LVI course").

227. On information and belief, Dr. Smith paid LVI for the LVI course, and the course was approved by LVI and taught by an LVI-approved instructor.

228. On information and belief, Dr. Smith paid FBI for the FBI course.

229. During the teaching of the LVI course, the agent, servant or employee of LVI who taught it made various representations about the safety and efficacy of AGGA.

230. During the teaching of the FBI course, Galella made various representations about the safety and efficacy of AGGA.

231. Defendant Galella, individually and as an agent, servant or employee of FBI, and the agent, servant or employee of LVI who taught the LVI course, during the teaching of the FBI course and the LVI course respectively, made various representations about the safety and efficacy of AGGA, which representations included those set forth above and which were unproven, not supported by medical knowledge or science, untested by any clinical trial, unsupported by peer-reviewed literature, and which were false and materially misleading.

232. On information and belief, the FBI course and/or the LVI course largely or completely comprised the extent of Dr. Smith's training concerning AGGA and CAB.

233. Prior to November 2018, Ms. Thompson sought treatment from Dr. Smith for a condition which, inter alia, was described as sleep apnea, and Dr. Smith prescribed treatment with an AGGA device in lieu of jaw surgery for the purpose of, *inter alia,* curing said sleep apnea and informed Ms. Thompson that, as AGGA caused her jaw to move forward, a more pleasing physical appearance would result as well.

234. At no time did FBI or Galella or LVI ever warn Dr. Smith or Ms. Thompson that, in regard to adult users, AGGA was unproven, was not supported by scientific or medical knowledge, was not reasonably safe, was unreasonably dangerous, was not efficacious, and presented a risk of serious and permanent injury to such consumers.

235. Prior to November 2018, Dr. Smith consulted with OrthoMatrix, through Dr. Galella and others, in regard to whether Ms. Thompson was an appropriate candidate for AGGA and CAB, and for the purpose of establishing an AGGA and CAB treatment plan.

236. More specifically, prior to November 2018, on information and belief, Dr. Smith submitted a questionnaire and dental records concerning Ms. Thompson to OrthoMatrix's Total Diagnostics internet portal, and thereafter and as a result, OrthoMatrix, through Dr. Galella and others, produced an AGGA/CAB treatment plan for Ms. Thompson ("the Thompson treatment plan") and otherwise represented to Dr. Smith and to Ms. Thompson that AGGA and CAB were appropriate treatments for Ms. Thompson.

237. Prior to November 2018, Dr. Smith, on information and belief in reliance on advice, instruction and guidance provided by OrthoMatrix and Dr. Galella, submitted information and/or specifications to John's Dental concerning Ms. Thompson and did place an order for an AGGA appliance to be manufactured by John's Dental for the specific use by Ms. Thompson.

238. Prior to November 2018, John's Dental did manufacture an AGGA appliance for use by Dr. Smith for installation in Ms. Thompson's mouth, did place it in the stream of commerce and did sell that appliance to Dr. Smith, who was then within Germany; John's Dental knew at the time it was placed into the stream of commerce that it would be installed in a member of the public, and specifically that Dr. Smith would install it in Ms. Thompson.

239. At the time of sale of the AGGA to Dr. Smith, John's Dental impliedly warranted and represented that the AGGA was fit, capable and suitable for the ordinary purposes for which it was intended, that it was fit for the specific purpose for which it was sold to Dr. Smith, that it had no design defects, that it was of merchantable quality, and that it was safe and not unreasonably dangerous.

240. Ms. Thompson reasonably relied upon the implied warranties of John's Dental, as well as on its skill and judgment.

241. Prior to the AGGA being placed into the stream of commerce and sold to Dr. Smith for use on Ms. Thompson, Dr. Galella did inspect and examine photographs of that AGGA device and of a mold of Ms. Thompson's teeth, and pronounced the AGGA fit to be used.

242. At the time of the sale of the AGGA to Dr. Smith, the AGGA was inherently defective by virtue of its design, was not fit for its intended purpose nor for the specific purpose for which it was sold for installation in Ms. Thompson's mouth; it was not of merchantable quality, was not reasonably safe, was unreasonably dangerous and defective, all at the time it left the possession, custody and control of John's Dental, for reasons that include but are not limited to:

a. AGGA as designed, manufactured and sold was not based on valid scientific principles, and in an adult does not change the nasomaxillary complex in three, or any, dimensions, does not stimulate new bone growth, does not move the maxilla forward horizontally by as much or more than 10 mm, does not open a user's airway, is in no way a substitute for jaw surgery in an adult;

b. AGGA is unreasonably dangerous in that, rather than move the maxilla or make any three-dimensional changes in the adult nasomaxillary complex, it pushes the

upper teeth forward and, after moving more than a limited amount, out of their safe position within the alveolar bone, causing the teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth;

c. While AGGA may have additional utility for children, the utility of AGGA in an adult is in its moving teeth a limited amount within the bone (a function that can be performed by other, standard orthodontic appliances), is far outweighed by the risks AGGA creates;

d. John's Dental failed to warn Dr. Smith or anyone else:

(i) of the limitations of AGGA's utility for adults in that it would move teeth through bone, but could not make three-dimensional changes in the adult nasomaxillary complex including that it cannot move or grow the maxilla, cannot open an adult user's airway, and is in no way a substitute for jaw surgery in an adult;

(ii) that AGGA should not be used for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move the maxilla;

(iii) that using AGGA for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move or grow the maxilla, could result in serious injury including causing teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth;

(iv) that claims made about AGGA making three-dimensional changes in the nasomaxillary complex of adults were contrary to medical science and unproven; and,

(v) if AGGA were used in an adult, the patient should be closely monitored to ensure it was not causing gum recession, root resorption or other injury indicative of excessive movement of teeth through bone.

243. At the time that John's Dental manufactured, placed into the stream of commerce and sold to Dr. Smith the AGGA appliance for Ms. Thompson, that appliance was not reasonably safe for use on adults, was not minimally safe for its expected purpose, and was dangerous to the extent beyond which would be contemplated by the ordinary dentist or consumer who purchases or uses it, with the ordinary knowledge common to such dentists or users.

244. At all times relevant to the Complaint, had Ms. Thompson been warned of the defects and deficiencies of AGGA as described above, she would not have embarked on any course of treatment using AGGA.

245. At all times relevant to the Complaint, had Dr. Smith been warned by any of the defendants of the defects and deficiencies of AGGA as described above then, on information and belief, he would not have embarked on any course of treatment of Ms. Thompson using AGGA.

246. At all times relevant to the Complaint, Ms. Thompson would not by exercise of ordinary and reasonable care have discovered the defects and deficiencies of AGGA as described above nor perceived its danger.

247. By the August 2019, Ms. Thompson became aware that the AGGA device that had been installed in her was causing severe and permanent injury, and she had the device removed.

248. At all times relevant to the Complaint, Dr. Galella and OrthoMatrix, and LVI, engaged in consumer-related conduct that was materially misleading in that: 1) each of them made material misrepresentations to dentists through the course and other courses, and through website marketing to both dentists and consumers, to the effect that AGGA was safe and efficacious for adults and was a reasonable and functionally effective alternative to jaw surgery for adults that would create three-dimensional changes in the adult nasomaxillary complex including movement of the maxilla; 2) such material misrepresentations were made with the knowledge and expectation that those dentists would advertise and otherwise offer AGGA as a safe and efficacious treatment alternative to adult consumers, including but not limited to consumers in Germany including Ms. Thompson; and, 3) such material misrepresentations were made with the knowledge and expectation that adult members of the general public would ask dentists for AGGA and/or otherwise accept AGGA as a safe and efficacious treatment alternative to jaw surgery, and were made to consumers, including but not limited to adult consumers in Germany including Ms. Thompson.

249. As a result of the installation and use of the AGGA appliances, Ms. Thompson has been caused to suffer significant and permanent injury and damage, including but not limited to: severe bone loss, loose teeth, the prospect of losing teeth, pain, economic loss related to the cost of said worthless and harmful AGGA treatment, prolonged suffering from the conditions for which she originally sought treatment from Dr. Smith as a result of being induced to avoid seeking proper treatment for it; and other injury and damage.

250. Ms. Thompson at all times relevant to the Complaint acted reasonably, and nothing she did or failed to do caused or contributed to cause her injuries.

COUNT XX:

Product Liability-Negligence Against Defendant Dr. Galella

251. Plaintiff Emily Thompson reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

252. Defendant Dr. Galella was negligent in that, *inter alia,* he:

a. Negligently designed the AGGA device that was installed in Ms. Thompson for use by adults, when he knew or should have known that AGGA devices, when used by adults to dimensionally change the nasomaxillary complex, were unproven, were neither safe nor efficacious, the principles upon which AGGA allegedly functioned were not supported by and were in contravention of medical knowledge and science, it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by Ms. Thompson;

b. taught the course to Dr. Smith, informing him and others that the AGGA device was safe and efficacious for use by adults, when he knew or should have known that the theory behind AGGA regarding its use on adults and its alleged function of making three-dimensional changes in the nasomaxillary complex including forward movement of the maxilla of adults, was contrary to his education and training, and to medical science, and was unproven, that AGGA was neither safe nor efficacious in regard to making three-dimensional changes in the nasomaxillary complex including forward movement of the maxilla of adults, that it had limited utility for adults, that it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by Ms. Thompson all as aforesaid; and,

c. marketed AGGA to Dr. Smith, to Ms. Thompson and to dentists and consumers throughout the world, as a product that was safe and efficacious for adults

when he knew or should have known that claims made about AGGA making three-dimensional changes in the nasomaxillary complex of adults was contrary to Galella's education and training, and to medical science, and was unproven, that AGGA was neither safe nor efficacious in regard to making three-dimensional changes in the adult nasomaxillary complex including forward movement of the maxilla, had limited utility for adults, that it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by plaintiff, all as aforesaid;

d. failed to warn purchasers of AGGA and dentists to whom he taught the course including Dr. Smith and other similar courses, or anyone else:

(i) of the limitations of AGGA's utility for adults in that it would move teeth through bone, but could not make three-dimensional changes in the adult nasomaxillary complex including that it cannot move or grow the maxilla, cannot open an adult user's airway, and is in no way a substitute for jaw surgery in an adult;

(ii) that AGGA should not be used for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move the maxilla;

(iii) that using AGGA for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move or grow the maxilla, could result in serious injury including, *inter alia,* causing teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth;

(iv) that claims made about AGGA making three-dimensional changes in the nasomaxillary complex of adults were contrary to medical science and unproven; and,

(v) if AGGA were used in an adult, the patient should be closely monitored to ensure it was not causing gum recession, root resorption or other injury indicative of excessive movement of teeth through bone.

253. Dr. Galella acted with reckless disregard for the safety of others, including Ms. Thompson.

254. As a direct and proximate result of the negligence of Dr. Galella, and his reckless disregard for the safety of others including Ms. Thompson, Ms. Thompson has been substantially and permanently injured and damaged as outlined above.

WHEREFORE, plaintiff Emily Thompson demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant Dr. Steve Galella, D.D.S., plus interest and costs.

COUNT XXI:

Negligence Against Defendant LVI

255. Plaintiff Emily Ms. Thompson reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

256. Defendant LVI was negligent in that, *inter alia,* it:

a. taught the course to Dr. Smith, informing him and others that the AGGA device was safe and efficacious for use by adults, when he knew or should have known that the theory behind AGGA regarding its use on adults and its alleged function of making three-dimensional changes in the nasomaxillary complex including forward movement of the maxilla of adults, was contrary to his education and training, and to

medical science, and was unproven, that AGGA was neither safe nor efficacious in regard to making three-dimensional changes in the nasomaxillary complex including forward movement of the maxilla of adults, that it had limited utility for adults, that it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by Ms. Thompson all as aforesaid; and,

b. marketed AGGA to Dr. Smith, to Ms. Thompson and to dentists and consumers throughout the world, as a product that was safe and efficacious for adults when it knew or should have known that claims made about AGGA making three-dimensional changes in the nasomaxillary complex of adults was contrary to to medical science, and was unproven, that AGGA was neither safe nor efficacious in regard to making three-dimensional changes in the adult nasomaxillary complex including forward movement of the maxilla, had limited utility for adults, that it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by Ms. Thompson, all as aforesaid;

c. failed to warn purchasers of AGGA and dentists to whom it taught the course including Dr. Smith and other similar courses, or anyone else:

(i) of the limitations of AGGA's utility for adults in that it would move teeth through bone, but could not make three-dimensional changes in the adult nasomaxillary complex including that it cannot move or grow the maxilla, cannot open an adult user's airway, and is in no way a substitute for jaw surgery in an adult;

(ii) that AGGA should not be used for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move the maxilla;

(iii) that using AGGA for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move or grow the maxilla, could result in serious injury including, inter alia, causing teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth;

(iv) that claims made about AGGA making three-dimensional changes in the nasomaxillary complex of adults were contrary to medical science and unproven; and,

(v) if AGGA were used in an adult, the patient should be closely monitored to ensure it was not causing gum recession, root resorption or other injury indicative of excessive movement of teeth through bone.

257. LVI acted with reckless disregard for the safety of others, including Ms. Thompson.

258. As a direct and proximate result of the negligence of LVI, and its reckless disregard for the safety of others including Ms. Thompson, Ms. Thompson has been substantially and permanently injured and damaged as outlined above.

WHEREFORE, plaintiff Emily Thompson demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant LVI, plus interest and costs.

COUNT XXII:

Negligence Against Defendant Orthomatrix And Defendant Galella

259. Plaintiff Emily Thompson reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

260. OrthoMatrix was negligent in that, *inter alia,* it, either directly or by or through its division or trade name FBI and/or OrthoLogic, produced the Thompson treatment plan for Ms. Thompson's dentist for the installation of an AGGA device, when it knew or should have known that the device, for use by adults, was unproven, it was neither safe nor efficacious, the principles upon which it allegedly functioned were not supported by and were in contravention of medical knowledge and science, it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by Ms. Thompson.

261. OrthoMatrix acted with reckless disregard for the safety of others, including Ms. Thompson.

262. Galella was negligent in that, inter alia, he produced the Thompson treatment plan for Ms. Thompson's dentist for the installation of an AGGA device, when he knew or should have known that the device, for use by adults, was unproven, it was neither safe nor efficacious, the principles upon which it allegedly functioned were not supported by and were in contravention of medical knowledge and science, it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by Ms. Thompson.

263. Galella acted with reckless disregard for the safety of others, including Ms. Thompson.

264. As a direct and proximate result of the negligence of OrthoMatrix, and Galella and their reckless disregard for the safety of others including Ms. Thompson, Ms. Thompson has been substantially and permanently injured and damaged as outlined above.

WHEREFORE, plaintiff Emily Thompson demands Judgment in an amount of in excess of One Hundred Thousand Dollars ($100,000.00) against defendant OrthoMatrix Corp., Inc. and defendant Galella, plus interest and costs.

COUNT XXIII:

Product Liability-Breach Of Warranties Against Defendant John's Dental

265. Plaintiff Emily Thompson reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

266. At the time that the AGGA device that was sold to Ms. Thompson's dentist last left the possession, custody or control of John's Dental, the device was inherently defective by virtue of its design, were not fit for its intended purpose nor for the specific purpose for which they were sold for installation in Ms. Thompson's mouth, were not of merchantable quality, were not reasonably or minimally safe, and were unreasonably dangerous and defective, all at the time each left the possession, custody and control of John's Dental, for reasons that were described above, in regard to its use by adults.

267. The defective nature of the AGGA devices includes their lack of warnings, at the time each last left the possession, custody and control of defendant John's Dental, in in that it failed to warn purchasers of AGGA, or anyone else:

a. of the limitations of AGGA's utility for adults in that it would move teeth through bone, but could not make three-dimensional changes in the adult nasomaxillary complex including that it cannot move or grow the maxilla, cannot open an adult user's airway, and is in no way a substitute for jaw surgery in an adult;

b. that AGGA should not be used for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move or grow the maxilla;

c. that using AGGA for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move or grow the maxilla, could result in serious injury including causing teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth.

d. that claims made about AGGA making three-dimensional changes in the nasomaxillary complex of adults were contrary to medical science and unproven; and,

e. if AGGA were used in an adult, the patient should be closely monitored to ensure it was not causing gum recession, root resorption or other injury indicative of excessive movement of teeth through bone.

268. When used for the purpose for which it was intended, AGGA has limited utility for adults and presents a risk of serious and permanent injury to adults when used as intended by the designer, manufacturer and seller to make dimensional changes in the nasomaxillary complex, all as aforesaid.

269. As a result of the foregoing, John's Dental was in breach of the implied warranties of merchantability and fitness for a particular purpose in regard to the aforesaid AGGA devices sold to Ms. Thompson's dentist and installed in Ms. Thompson's mouth.

270. Ms. Thompson relied on the aforementioned implied warranties in agreeing to the installation of the AGGA devices.

271. As a direct and proximate result of those breaches of implied warranties, separately and together, Ms. Thompson has been substantially and permanently injured and damaged as outlined above.

WHEREFORE, plaintiff Emily Thompson demands Judgment in an amount of in excess of One Hundred Thousand Dollars ($100,000.00) against defendant John's Dental Laboratory, Inc., plus interest and costs.

COUNT XXIV:

Product Liability- Negligence Against Defendant John's Dental

272. Plaintiff Emily Thompson reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

273. At the time the AGGA device was sold by to John's Dental to Ms. Thompson's dentist, John's Dental knew or should have known that the device, for use in adults, was not reasonably safe, were negligently designed and in a condition not reasonably contemplated by Ms. Thompson, the ultimate user, including for the reasons that the function for which it was designed was not possible to achieve and was in contravention of principles of physiology and anatomy, and carried substantial risk of serious injury for adults.

274. At the time the AGGA device was sold by John's Dental to Ms. Thompson's dentist, the product posed a substantial likelihood of harm to Ms. Thompson or any other user and was unreasonably dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it with the ordinary knowledge common to consumers, including because the product's tendency when used in adults, rather than to move the maxilla, is to push the upper teeth forward and out of their proper position within the alveolar bone, causing the teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth, all as happened to Ms. Thompson as a result of the use of the product.

275. No reasonable person who knew the risk of harm of using AGGA at the time of manufacture would conclude that the benefit of the product outweighed the risk to users.

276. The negligent and defective design of the AGGA device installed in Ms. Thompson's mouth was the sole and/or substantial cause and/or factor in bringing about her injuries or damages.

WHEREFORE, plaintiff Emily Thompson demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant John's Dental Laboratory, Inc., plus interest and costs.

COUNT XXV:

SECTION 823 OF GERMAN CIVIL CODE AND GERMAN PRODUCT LIABILITY ACT (PRODHAFTG)

277. Plaintiff Emily Thompson reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

278. Section 823 of German Civil Code and the German Product Liability Act make unlawful any deceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in Germany.

279. John's Dental has engaged in consumer-oriented conduct that is materially misleading, in that it has, in the course of marketing AGGA to consumers (including German consumers) directly, and to dentists (including German dentists) for the purpose of enticing consumers (including German consumers) to use AGGA, represented falsely that:

a. AGGA is a device that mechanically causes the maxilla to move forward over time;

b. that by touching and thereby stimulating a nerve in the upper palate, AGGA causes new bone to grow at the maxillary tuberosity (the most distal aspect of the upper jaw) and other places, which in turn causes the maxilla to move forward, effectively lengthening the upper jaw;

c. that as the maxilla moves forward, upper teeth move with it;

d. that by adhering bite plates to the lower molars, the lower jaw moves forward as the upper jaw moves forward;

e. that the movement of the jaws has the effect of opening the airway, and moving the jaws into a position more natural for the user's face;

f. is reasonably safe for installation into dental patients' mouths; and,

g. can be utilized as a substitute for jaw surgery.

280. These false representations are material in that they go to the essence of the function of AGGA as claimed by John's Dental, and their falsity means that the product is useless.

281. AGGA is unreasonably dangerous as designed and manufactured, and can cause substantial and permanent damage, as set forth above.

282. As a direct and proximate result of the aforementioned material misrepresentations, Ms. Thompson allowed AGGA to be installed in her mouth, and as a result suffered serious and permanent injury as described above.

283. This conduct of John's Dental has affected and will continue to affect not just Ms. Thompson but also consumers at large within Germany who seek to reconfigure their jaws for a host of reasons including resolving issues of insufficient airway, severe dental crowding, disfigurement of chin or jawline or other reasons.

284. This conduct of John's Dental has also affected and will continue to affect German dentists who, based on those misrepresentations, will utilize AGGA on German consumers and thereby visit substantial and permanent injury on such consumers who seek to

reconfigure their jaws for a host of reasons including resolving issues of insufficient airway, severe dental crowding, disfigurement of chin or jawline or other reasons.

285. John's Dental, through its material misrepresentations, has violated SGA and CPA, thereby causing Ms. Thompson severe and permanent injury and damage as described above.

WHEREFORE, plaintiff Emily Thompson demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant John's Dental Laboratory, Inc., plus treble damages, attorney's fees interest and costs.

JURY TRIAL DEMAND

Plaintiffs hereby demand a trial by jury on all Counts so triable.

WHEREFORE, Plaintiffs pray for judgment against Defendants, jointly and severally, as follows:

1. For compensatory damages in excess of $100,000.00;
2. For punitive damages in an amount to be proven at trial;
3. For attorney's fees and costs of suit incurred herein;
4. For pre-judgment and post-judgment interest as allowed by law; and
5. For such other and further relief as is appropriate under the circumstances.

Respectfully submitted,

s/Alan C. Milstein
Alan C. Milstein, Esquire
SHERMAN, SILVERSTEIN, KOHL, ROSE & PODOLSKY, P.A.
308 Harper Drive, Suite 200
Moorestown, NJ 08057
Telephone: 856-662-0700
Facsimile: 856-488-4744
Email: amilstein@shermansilverstein.com

s/Scott E. Charnas
Scott Charnas, Esquire (Admission Pending)
CHARNAS LAW FIRM, P.C.
455 East 51st Street
New York, NY 10022
Tel: 212-980-6800
Email: scharnas@charnaslawfirm.com
Attorneys for Plaintiffs

Dated: **September 30, 2021**